
INFORMATION TECHNOLOGY

MANAGEMENT OF CDER INFORMATION TECHNOLOGY COORDINATING COMMITTEE

CONTENTS

PURPOSE
BACKGROUND
ORGANIZATION
RESPONSIBILITIES
PROCEDURES
EFFECTIVE DATE

PURPOSE This MAPP describes :

- The organization and responsibilities of the Information Technology Coordinating Committee (ITCC) and it's work groups;
 - The procedures to be used in designating members to serve on the ITCC;
 - The responsibilities of those designated to serve on the ITCC; and
 - The procedure for bringing issues to the ITCC.
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BACKGROUND

Throughout the Center for Drug Evaluation and Research (CDER), committees and work groups form to address various issues that affect the Center. To operate effectively, the objectives of each committee and work group, and the responsibilities of its members must be consistent with CDER's mission, vision, operating principles, and priorities. To establish and maintain consistent information technology strategic planning and policy across the Center, and to ensure effective use of staff resources to address IT needs and emerging problems, CDER has established the Information Technology Coordinating Committee.

REFERENCES

- CDER MAPP 4510.1, *Authorization, Funding, and Tracking Speeches/Participation on Planning Committees*, November 7, 1995.
 - CDER MAPP 4510.2, *Clearance of Speeches, Articles, and Other Communication Material*, November 7, 1995.
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ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There will be some fluctuations as necessary given membership and workload demands.

- **ITCC**
 1. **Chair** - The ITCC is chaired by the Center Director or designee. The initial term for a designee will be two years but the incumbent may be reappointed by the Center Director.
 2. **Executive Secretary** - The chair may act as the Executive Secretary or appoint a full-time or part-time Executive Secretary on an yearly basis.
 3. **ITCC Committee Members** - Committee members are appointed by the ITCC Chair and are primarily key Center-level decision-makers or their designees. Each member will serve a two year term. However, the members may be reappointed by the ITCC Chair.
 4. **Other Participants** - The ITCC Chair may also appoint observers and experts from any office, division, or government or non-government organization to facilitate discussions regarding identified issues.

- **Ad hoc Work Groups**

Whenever feasible, the ITCC will rely on standing CDER IT Committees (e.g. the Office of Review Management (ORM) and the Office of Pharmaceutical Sciences (OPS) IT Committees) to help further define a problem, investigate alternatives, and recommend solutions. The ITCC may also form ad hoc work groups.

1. **Chair and Co-Chair** - The ITCC will select from the ITCC membership a chairperson and a co-chair for each work group taking

into account expertise and interest in the subject matter, and organizational and management skills.

Each chairperson should serve as the work group chair for the duration of the project. The ITCC Chair may, in unusual circumstances, decide to reduce or extend the working group chair's term.

2. **Membership** - The membership selection by the work group chair will be based upon the candidate's qualifications, expertise and interest in the subject matter. The work group chair must also consider the candidate's workload, and the time-demands caused by membership on other committees. The selections are subject to review by the ITCC.

Work group membership should be kept small when possible (10 or fewer).

RESPONSIBILITIES

- **The ITCC is responsible for the oversight of the following IT related activities in CDER:**
 1. Development, maintainance, and implementation of the CDER IT strategic plan;
 2. Development and implementation of CDER-wide information technology policies and procedures;
 3. Monitoring and facilitating the efforts of IT related committees (e.g. the ORM IT Group, and the OPS IT Group) throughout CDER;
 4. Clearance of material (speeches, articles, etc) that represents CDER-wide IT policies, and authorization of funding requests for CDER staff to participate in meetings where they represent CDER-wide IT policies (MaPP 4410.1 and 4510.2);
 5. Resolution of intracenter information technology policy disputes, and addressing intercenter IT issues; and
 6. Communication and promotion of CDER-wide IT efforts within and outside the agency.

- **The Executive Secretary is responsible for:**

1. Arranging and organizing ITCC meetings. Issues to be brought before the ITCC should be directed to the attention of the Executive Secretary who will schedule them in consultation with the chair of the ITCC;
2. Distributing meeting related background documents;
3. Maintaining files of ITCC action items and resolution, budget, work group activities, and activities of IT related groups and committees throughout CDER;
4. Preparing, distributing, and filing meeting minutes. Minutes will be filed on the common CDER shared drive.

- **ITCC formed work groups are responsible for:**

1. Serving as a source of advice and assistance to ITCC in matters pertaining to information technology issues that are within their areas of expertise; and
2. Developing, as determined by the ITCC, policies and procedures related to matters within their areas of expertise.

- **Chairs of work groups are responsible for:**

1. Attending ITCC meetings to discuss the status of any tasks in which they are engaged;
2. Developing time frames for completion of projects and forwarding them to ITCC for concurrence. Based on CDER-wide resources and priorities, the ITCC may amend the time frames of the project;
3. Obtaining input from the ITCC on proposed policy documents prior to review by or "negotiations with" organizations outside of FDA (e.g., trade associations);
4. Scheduling and conducting agenda-based meetings of the work group as required to fulfill the work group's objectives; and
5. Preparing brief minutes of each meeting, distributing them to work group members, and filing them on the designated shared drive under

the subdirectory established for each work group. For those work group chairs who do not yet have access to the designated shared drive, minutes should be provided to the Executive Secretary on diskette for filing on the shared drive;

- **Members of work groups are responsible for:**

1. Representing their division's/office/committee views on issues under consideration by the work group;
2. Communicating with their division/office/committee management about the deliberations of the work group; and
3. Regularly attending the meetings of the work group for which they are the designated representatives. If they cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the work group chair.

PROCEDURES

- **Creation of New Work Groups**

The ITCC will form work groups as needed. Requests from outside of the ITCC to form a work group to address a CDER-wide IT issue should be made in writing (see Attachment A) to the ITCC and should be signed by a first-line or higher level supervisor in CDER.

A request to form a work group to address an issue that affects the Center as a whole should be accompanied by a statement of the proposed objectives, the names of persons who might participate as members, chair, and co-chair, the frequency of meetings, the expected life of the group, and the term of its members and the expected method of replacement.

The ITCC will determine, based on CDER's IT strategic plan, priorities, and resources, whether the work group should be established or integrated with an existing CDER work group. A list of current work group members will be maintained by the ITCC.

The ITCC should be notified of changes in the membership or objectives of a work group.

- **Disbandment of Work Groups**

The ITCC will monitor work groups to determine whether any of the work groups should be disbanded or the membership or chair changed. The ITCC should disband a committee or work group when:

1. It reaches the end of its scheduled lifetime;
2. It has fulfilled its objectives; or
3. The work group no longer performs a useful function

A copy of this notice will be filed in the appropriate subdirectory on the share drive with the title "FINAL."

- **Communications With ITCC members**

1. Activities of the ITCC should be communicated to the staff in CDER through distribution and electronic filing of the minutes of the ITCC and work group meetings.
 2. CDER staff may raise issues to the ITCC by bringing them to the attention of the Executive Secretary or any member of the ITCC.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.